

COMPLAINT AND
JURY DEMAND

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Plaintiff MYL Litigation Recovery I LLC (collectively, “Plaintiff”) is the assignee of entities that purchased the common stock of Mylan N.V. (“Mylan,” or the “Company”). Plaintiff, through its undersigned attorneys, by way of this Complaint and Jury Demand, for its federal securities claims against Mylan, its predecessor, and its present and former executive officers Heather Bresch, Paul B. Campbell, Rajiv Malik, Kenneth S. Parks, and John D. Sheehan (the “Individual Defendants,” and, collectively with Mylan and its predecessor, the “Defendants”), allege the following upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters.

Plaintiff’s information and belief is based on, *inter alia*, an investigation by its attorneys, which investigation includes, among other things, a review and analysis of: Mylan’s filings with the United States Securities and Exchange Commission (“SEC”); public documents and media reports concerning Mylan; analyst reports concerning Mylan; transcripts of conference calls and earnings calls involving Defendants; pleadings, motion papers, and exhibits to declarations filed in the matter *In re Mylan N.V. Securities Litigation*, 16-cv-07926 (JPO) (S.D.N.Y.) (the “Class Action”); and documents filed in the matter *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation*, MDL 2785 (D. Kan.) (the “EpiPen Antitrust Action”). Many of the facts supporting the allegations contained herein are known only to Defendants or are exclusively within their custody and/or control. Plaintiff believes that further substantial evidentiary support will exist for the allegations in this Complaint after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is an action to recover significant investment losses suffered as a result of numerous false and misleading statements made by Mylan and its senior executives about a life-saving medication called the “EpiPen.”

2. The EpiPen is an “auto-injector” pen that is used to inject people suffering from a severe allergic reaction with “epinephrine” to counteract the effects of the allergic reaction. The EpiPen is used by individuals, many of whom are children, who have severe allergies to substances such as peanuts, shellfish, and bee stings. When exposed to these allergens, at-risk individuals can suffer shortness of breath and swelling that, if left untreated for even a short period of time, may result in death. Thus, the EpiPen is an essential medical device to which potential victims of severe allergy attacks must have access at all times.

3. A significant portion of Mylan’s sales of the EpiPen are funded by Medicaid. Medicaid is a government assistance program that provides healthcare services and prescription drug coverage to low-income families. Under established federal law, drug manufacturers are required to pay rebates to the government for sales funded by Medicaid. The amount of the Medicaid rebate is determined by a simple statutory formula. For brand-name drugs, such as the EpiPen, the amount of the rebate is at least 23% of the price. For generic drugs, on the other hand, the amount of the rebate is only 13% of the price.

4. Unbeknownst to investors, between 2007 and 2016, Mylan misclassified the EpiPen as a generic drug in order to improperly reduce the size of the rebates that it owed Medicaid. Although Mylan externally marketed the EpiPen as a brand-name drug and federal law required Mylan to classify the EpiPen as a brand-name drug for purposes of the Medicaid rebate, Mylan calculated the rebate on the EpiPen as if it were a generic drug. By paying Medicaid a smaller rebate, Mylan was able to inflate the revenues and profits that it recorded

from sales of the EpiPen. This intentional misclassification of the EpiPen by Mylan cost U.S. taxpayers – who fund Medicaid – over a billion dollars.

5. Also unbeknownst to investors, Mylan engaged in anticompetitive conduct to control the market for epinephrine auto-injectors. Specifically, Mylan paid large rebates to Pharmacy Benefit Managers to ensure that potential competitors to the EpiPen were not covered by a patient's prescription drug plan. Thus, patients who needed an epinephrine auto-injector had to either accept the EpiPen or pay out-of-pocket for another epinephrine auto-injector. By engaging in this anticompetitive conduct, Mylan was able to maintain an effective monopoly over the epinephrine auto-injector market, which in turn allowed Mylan to drastically raise the price of the EpiPen from less than \$100 to over \$600.

6. Defendants made material misrepresentations and failed to disclose material information about Mylan's marketing and sale of the EpiPen. Defendants did this by: (1) purporting to provide explanations in Mylan's SEC reports about how the EpiPen contributed to Mylan's financial performance, but without apprising the market that these figures were grossly inflated because Mylan had not paid hundreds of millions of dollars in rebates that it owed Medicaid as a result of its intentional misclassification of the EpiPen; (2) misleading the investing public that Mylan was paying the correct rebate amount to Medicaid for the EpiPen when, in fact, Mylan was drastically underpaying Medicaid the rebates it owed on EpiPen sales funded by U.S. taxpayers; (3) lying to investors about Defendants' knowledge of the EpiPen misclassification; (4) cautioning the market that improper classification of the EpiPen could lead to lead to regulatory scrutiny without informing investors that Mylan was under investigation already for misclassifying the EpiPen; (5) falsely asserting that the market for the EpiPen was very competitive without disclosing the anticompetitive conduct in which Mylan was engaging

with respect to the EpiPen; and (6) incorrectly certifying that Mylan had effective disclosure controls and procedures when, in fact, such internal controls were virtually non-existent.

7. The truth about Mylan's improper practices with respect to the marketing and sale of the EpiPen gradually was revealed in late 2016. As Mylan kept raising the price of the EpiPen, Congressional scrutiny of Mylan's conduct increased. This increased scrutiny led to information about Mylan's improper conduct slowly being leaked into the market. In a letter to Congress, the acting head of the Centers for Medicare & Medicaid Services revealed that it had told Mylan repeatedly to change its classification of the EpiPen for purposes of the Medicaid rebate, but that Mylan had blatantly ignored that demand. Indeed, Mylan had been under investigation by the Department of Justice for its EpiPen practices since 2014. That investigation resulted in Mylan agreeing to repay the government almost half a billion dollars. Mylan also entered into a Corporate Integrity Agreement with the Office of Inspector General for the Department of Health and Human Services, pursuant to which Mylan agreed to make significant changes to its internal controls to improve its compliance and reporting systems.

8. As information about Defendants' misclassification of the EpiPen and anticompetitive conduct was slowly leaked to the market, the price of Mylan common stock plummeted from \$48 per share to \$37 per share between August and October of 2016.

9. Plaintiff is the assignee of investment funds that purchased significant amounts of Mylan common stock in the United States between October 28, 2015 and October 6, 2016, during the time when Defendants, unbeknownst to the investing public, were making false and/or fraudulent statements about the EpiPen. As a series of partial but inadequate disclosures about the EpiPen was released to the market, investors suffered significant losses.

10. Plaintiff now brings this action to recover the damages suffered as a result of Defendants' materially false and misleading misstatements and omissions.

JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to Sections 10(b), 18 and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b), 78r and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

12. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1331.

13. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391. Many of the acts giving rise to the violations complained of herein, including the dissemination of false and misleading information, occurred in this District.

14. In connection with the acts, transactions and conduct alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mails, interstate telephone communications and the facilities of a national securities exchange and market.

PARTIES

I. Plaintiffs

15. Plaintiff MYL Litigation Recovery I LLC is a Delaware limited liability company with its main office location in New York, New York. Plaintiff is the assignee of federal securities law claims of investment entities under common management that purchased Mylan common stock in the United States (each an "Assignor" and collectively, the "Assignors"). Each Assignor is a member of Plaintiff, and Greenlight APE, LLC is the manager of Plaintiff.

16. The Assignors validly and irrevocably assigned their claims under the federal securities laws arising from their purchases of Mylan common stock to Plaintiff pursuant to an

Operating Agreement dated as of February 21, 2019 (the “Operating Agreement”). Specifically, Section 3.04 of the Operating Agreement provides in pertinent part:

Each [Assignor] hereby irrevocably transfers, assigns and delivers to [Plaintiff] all of their respective rights, title and interest, free and clear of any liens, security interests, encumbrances and restrictions of any kind whatsoever, in all claims and causes of actions, whether arising under federal, state or foreign law, related to the [Assignors]’ purchases and sales of securities issued by [Mylan] and/or any of its corporate affiliates during the period between October 28, 2015 and October 31, 2017, (inclusive).

17. By virtue of Section 3.04 of the Operating Agreement, Plaintiff holds the assigned interest in the causes of action alleged herein under Sections 10(b), Section 18, and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

18. Pursuant to the Operating Agreement, Assignor Greenlight Capital, LP validly and irrevocably assigned to Plaintiff its claims under the federal securities laws arising from its purchases of Mylan common stock in the United States. The dates on which Greenlight Capital, LP purchased Mylan common stock during the relevant period are attached hereto as Exhibit A.

19. Pursuant to the Operating Agreement, Assignor Greenlight Capital Qualified, LP validly and irrevocably assigned to Plaintiff its claims under the federal securities laws arising from its purchases of Mylan common stock in the United States. The dates on which Greenlight Capital Qualified, LP purchased Mylan common stock during the relevant period are attached hereto as Exhibit B.

20. Pursuant to the Operating Agreement, Assignor Greenlight Capital Investors, LP validly and irrevocably assigned to Plaintiff its claims under the federal securities laws arising from its purchases of Mylan common stock in the United States. The dates on which Greenlight Capital Investors, LP purchased Mylan common stock during the relevant period are attached hereto as Exhibit C.

21. Pursuant to the Operating Agreement, Assignor Greenlight Capital Offshore Partners validly and irrevocably assigned to Plaintiff its claims under the federal securities laws arising from its purchases of Mylan common stock in the United States. The dates on which Greenlight Capital Offshore Partners purchased Mylan common stock during the relevant period are attached hereto as Exhibit D.

22. Pursuant to the Operating Agreement, Assignor Greenlight Capital Offshore Master, Ltd. validly and irrevocably assigned to Plaintiff its claims under the federal securities laws arising from its purchases of Mylan common stock in the United States. The dates on which Greenlight Capital Offshore Master, Ltd. purchased Mylan common stock during the relevant period are attached hereto as Exhibit E.

23. Pursuant to the Operating Agreement, Assignor Solasglas Investments, LP (as successor to Greenlight Reinsurance, Ltd.) validly and irrevocably assigned to Plaintiff its claims under the federal securities laws arising from its purchases of Mylan common stock in the United States. The dates on which that common stock was purchased during the relevant period are attached hereto as Exhibit F.

24. At all relevant times, Greenlight Capital, Inc., DME Capital Management, LP or DME Advisors, LP (collectively, “Greenlight”) provided investment advisory services to the Assignors in connection with their purchases of Mylan common stock.

II. Defendants

25. Since February 27, 2015, Defendant Mylan has been a Dutch corporation with its headquarters in Hatfield, England. Previously, Mylan was a U.S. corporation based near Pittsburgh, Pennsylvania. In early 2015, Mylan Inc. (Mylan’s predecessor) acquired Abbott Laboratories and completed a corporate inversion, with the resulting corporation incorporated in the Netherlands. Mylan describes itself in its SEC filings as “a leading global pharmaceutical

company, which develops, licenses, manufactures, markets and distributes generics, branded generics, brand name and over-the-counter (“OTC”) products in a variety of dosage forms and therapeutic categories.” Mylan’s common stock is publicly traded in the United States on the NASDAQ Stock Market (the “NASDAQ”) under the ticker symbol “MYL.”

26. Defendant Mylan Inc., a subsidiary of Mylan N.V., is a Pennsylvania corporation with a principal place of business in Canonsburg, Pennsylvania.

27. Defendant Heather Bresch (“Bresch”) is Mylan’s Chief Executive Officer (“CEO”) and a member of its Board of Directors (“Board”). Bresch has worked for Mylan for more than a quarter of a century, holding roles in many different areas of the Company. Bresch became CEO of Mylan in January 2012. Prior to becoming CEO, Bresch served as President, where she was responsible for Mylan’s day-to-day operations. Before that, she served as Chief Operating Officer and Chief Integration Officer.

28. Defendant Paul B. Campbell (“Campbell”) was appointed as Mylan’s Chief Accounting Officer (“CAO”) in November 2015. Campbell served as the Company’s Senior Vice President and Controller since May 2015, holding roles of increasing responsibility at Mylan since 2002, including: Head of Global Operations Finance, Producers; Vice President, Global Operations Finance; and Vice President, Global Tech Operations Finance. Prior to 2010, Campbell held various other positions at Mylan, including Director of Internal Audit, Vice President Global Accounting and Reporting and Vice President and Assistant Controller.

29. Defendant Rajiv Malik (“Malik”) is Mylan’s President and has served as a Mylan executive since 2007. He served as Head of Global Technical Operations from January 2007 to July 2009, and then Executive Vice President and Chief Operating Officer from July 2009 to

December 2012. When Defendant Bresch took over the CEO role, Malik took over as President of Mylan.

30. Defendant Kenneth S. Parks (“Parks”) became Chief Financial Officer (“CFO”) of Mylan in June 2016, taking over the role, previously served by Defendant Sheehan, responsible for all of Mylan’s global finance functions including accounting and control, financial planning and analysis, investor relations, treasury and tax.

31. Defendant John D. Sheehan (“Sheehan”) served as Mylan’s CFO from April 2010 to April 2016.

FACTUAL ALLEGATIONS

I. Mylan and the EpiPen

32. Mylan is a pharmaceutical company that sells prescription and over-the-counter medicines. Mylan became a public company in 1973.¹

33. By 2002, Mylan’s annual revenues from its drug sales were over \$1 billion. By 2008, its annual revenues exceeded \$5 billion and, by 2016, they exceeded \$10 billion.

34. Two of Mylan’s primary products are the EpiPen® (epinephrine injection, USP) Auto-Injector and the EpiPen Jr® (epinephrine injection, USP) (collectively, the “EpiPen”).

35. The EpiPen is a device for injecting epinephrine into a person suffering from a severe allergic reaction.

36. Individuals who are allergic to certain foods (and other allergens, such as bee stings) can suffer anaphylaxis when exposed to those substances. Symptoms of anaphylaxis include swelling, vomiting, and difficulty breathing. If left untreated, anaphylaxis can result in death.

¹ References to “Mylan” throughout this Complaint shall be deemed to be to Mylan N.V. and/or its predecessor, Mylan Inc., as the context so requires.

37. Approximately 4.6% of people in the US suffer from food allergies, including 1 in 13 children.

38. Anaphylaxis can be treated by injecting a person having a severe allergic reaction with epinephrine. Epinephrine is manufactured adrenaline. Although epinephrine has been around for a long time, the EpiPen was the first device to allow patients to easily and quickly self-administer the medication with an auto-injector pen.

39. An epinephrine injection must be administered immediately in order to be effective. As a result, doctors typically recommend that adults and the parents of children susceptible to anaphylaxis carry with them a prefilled epinephrine auto-injector, which is available only by medical prescription, such as the EpiPen.

40. The EpiPen was approved by the FDA in the late 1980s. At that time, it was manufactured by Survival Technology, Inc., which later became Meridian Medical Technologies, Inc. (“Meridian”). King Pharmaceuticals (“King”) acquired Meridian in 2002, and Pfizer purchased King in 2010.

41. In 1997, Meridian sold the exclusive rights to market and distribute the EpiPen to Dey Pharma, a subsidiary of Merck. Mylan acquired the rights to market and distribute the EpiPen from Merck in 2007.

42. There are numerous patents covering the EpiPen. These patents do not expire until September 2025.

43. Since Mylan acquired the rights to market and distribute the EpiPen, it has sought to vigorously enforce these patents, through litigation and other means, to protect the EpiPen from potential competition. For example, in 2009, Mylan filed a patent infringement action against Teva Pharmaceuticals (“Teva”) for trying to market a generic version of the EpiPen. As

part of a settlement of that litigation, Teva allegedly agreed to delay the release of its generic epinephrine auto-injector.

44. Similar lawsuits were filed in 2010 and 2011 against Sandoz and Intelliject, respectively, both of which attempted to introduce epinephrine auto-injectors into the market to create competition for the EpiPen.

45. Recent government actions have increased demand for epinephrine auto-injectors. In 2010, the FDA changed labeling rules to allow epinephrine auto-injectors to be marketed to anyone at risk, rather than only those who had already suffered anaphylaxis.

46. That same year, the National Institute of Allergy and Infectious Diseases (“NAID”) released guidelines that make epinephrine auto-injectors the preferred treatment for severe allergic reactions, and that require epinephrine auto-injectors be sold in packages of two.

47. Then, in November 2013, Congress enacted the School Access to Emergency Epinephrine Act, which incentivizes schools to have epinephrine auto-injectors available to students.

48. When Mylan first started selling the EpiPen, its price was \$94. By 2016, Mylan was charging more than \$600 for the EpiPen.

49. The EpiPen constitutes a significant part of Mylan’s business. According to Mylan’s filing with the SEC, EpiPen sales accounted for a substantial percentage of Mylan’s annual earnings from operations:

	2014	2015	2016
EpiPen Operating Profit²	\$525,000,000	\$498,000,000	\$671,000,000
Mylan Earnings from Operations	\$1,352,600,000	\$1,460,900,000	\$701,600,000
Percentage	39%	34%	96%

² Based on September 26, 2016 Mylan filing with SEC.

50. Indeed, Defendants consistently made statements about the importance of the EpiPen to Mylan's business. For example, in its 2014 Annual Report, Mylan described the EpiPen as follows:

The EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer Inc. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector. *The strength of the EpiPen® brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our leadership position within this therapeutic category.*³

II. Pharmacy Benefit Managers

51. In the modern pharmaceutical industry, pharmacy benefit managers, or "PBMs," play a significant role.

52. PBMs are third-party administrators of prescription drug programs for commercial healthcare plans, self-insured employer healthcare plans, federal government employee healthcare plans, and state government employee healthcare plans.

53. PBMs are extremely important to pharmaceutical companies because it is the PBMs that dictate whether a drug is covered by a patient's insurance. PBMs do this by creating "formularies," which list the prescription drugs included in the insurance plan and set the pricing

³ Unless otherwise noted, bold, italic emphasis has been added to quotations.

tiers for those drugs. If a drug is not included on the formulary, it is not covered by insurance, and will likely be too expensive for a patient to purchase.

54. In addition to developing and maintaining the formulary, PBMs contract with pharmacies, negotiate discounts and rebates with drug manufacturers, and process and pay prescription drug claims.

55. The three largest PBMs – ExpressScripts, CVS Caremark, and OptumRx – control approximately 80% of the PBM market in the U.S.

56. The overwhelming majority of epinephrine auto-injector prescriptions in the U.S. are filled by commercial third-party payors whose formulary is controlled by a PBM. Thus, a drug manufacturer's access to PBMs is critical if it wants to compete in the epinephrine auto-injector market.

III. Medicaid Drug Classification and Rebates

57. Medicaid is a public assistance program that provides healthcare coverage for those members of society who cannot afford healthcare. All states, the District of Columbia, and the U.S. territories have Medicaid programs designed to provide healthcare coverage for low-income individuals.

58. Medicaid is funded by U.S. taxpayers.

59. Medicaid accounts for 17% of all U.S. healthcare expenditure. More than 70 million people are covered by Medicaid, including over 30 million children.

60. EpiPen prescriptions paid for by Medicaid are a significant source of income for Mylan.

61. From January 2011 through June 2015, Medicaid reimbursed approximately 2.6 million EpiPen prescriptions, an average of over 500,000 per year. Between 2011 and 2015,

Medicaid's total expenditure on EpiPen was almost \$960,076,576, which amounted to \$797 million after rebates paid by Mylan.

62. Section 1927 of the Social Security Act requires drug manufacturers to enter into a rebate agreement with Medicaid. This requirement has resulted in the establishment of the Medicaid Drug Rebate Program ("MDRP").

63. The MDRP requires a drug manufacturer to enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services ("HHS") in exchange for state Medicaid coverage of the manufacturer's drugs.

64. Drug manufacturers must submit product and pricing data concerning their drugs to the Centers for Medicare & Medicaid Services ("CMS") via the Drug Data Reporting for Medicaid system.

65. Prescription drugs marketed in the United States must be approved by the Food and Drug Administration ("FDA").

66. A new brand-name drug must be submitted to the FDA for approval under a New Drug Application ("NDA"). A NDA must contain extensive data gathered from animal studies and human clinical trials.

67. Generic drugs, on the other hand, are submitted to the FDA for approval under an Abbreviated New Drug Application ("ANDA"). ANDAs generally do not include data gathered from animal studies and human clinical trials, but contain data to scientifically demonstrate that the generic drug performs in the same manner as the brand-name drug.

68. When submitting information to CMS, manufacturers classify their drugs as either single source ("S" drugs), innovator multiple source ("I" drugs), or non-innovator multiple

source (“N” drugs). The classification of the drug dictates how the rebate owed is calculated for that drug under the MDRP.

69. Since 1990, the law has been clear as to how to classify drugs. If a drug is approved under a NDA, it should be classified as either an S drug or an I drug. If a drug is approved under an ANDA, on the other hand, it should be classified as a N drug. *See* 42 U.S.C. § 1396r-8(k)(7).

70. The difference between an S and an I drug is the existence of therapeutic equivalents. A drug approved under a NDA that has no therapeutic equivalents is an S drug, whereas a drug approved under a NDA that has therapeutic equivalents is an I drug.

71. CMS has repeatedly stated in its manufacturer releases that only drugs approved under an ANDA can be classified as a N drug. Specifically, CMS has informed pharmaceutical companies that:

In general, those products that are approved under a New Drug Application (NDA) need to be reported to CMS as either single source (S) or innovator multiple source (I) and those products approved under an Abbreviated New Drug Application (ANDA) need to be reported to CMS as non-innovator multiple source (N).

We encourage manufacturers to ***check the FDA’s [National Drug Code (“NDC”)] Directory*** to determine whether the correct application number has been reported to the FDA for the product or ***to identify the correct drug category for the product based on the application number assigned to the product***. Manufacturers may search by NDC Number and search by Labeler Code Only to view the FDA’s application number assigned to the NDC of the product.

Manufacturers may also access the FDA’s Drugs@FDA to determine whether a product was approved under a NDA or ANDA. Under this option, manufacturers may need the FDA’s application number retrieved from the FDA’s NDC Directory. The Drug Details information on Drugs@FDA should identify the product brand name(s) and active ingredient(s) approved under the specific application number and what type of application it is approved under (NDA or ANDA).

72. The National Drug Code Directory clearly states that the EpiPen was approved under a NDA (NDA019430), and not under an ANDA.

73. Moreover, until recently (when, in August 2018, the FDA approved Teva's generic epinephrine auto-injector), the EpiPen has never had an FDA-approved therapeutic equivalent.

74. In April 2016, CMS modified the classification rule and created a "narrow exception" to allow a drug approved pursuant to a NDA to be classified as a N drug if CMS expressly authorizes the manufacturer to do so. However, CMS was clear it will not grant the exception to drugs, such as the EpiPen, that have received patent protection or statutory exclusivity.

75. Drug manufacturers are responsible for paying to the government the applicable rebate on those drugs after receiving payment for the drugs from Medicaid programs.

76. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the federal government to offset the overall cost of prescription drugs under Medicaid.

77. When a brand-name drug is first approved by the FDA, there is a period of exclusivity that allows the drug manufacturer to set the price. Once generic equivalents of the brand-name drug enter the market, however, the brand-name drug typically loses its competitive advantage. Indeed, it is not unusual for a pharmacist to automatically substitute an available generic equivalent for a brand-name prescription because of the lower price of the generic drug.

78. The amount of the Medicaid rebate is based on a statutory formula. Because generic drugs are cheaper than brand-name drugs, the rebate percentage on a generic drug is a lot lower than the rebate percentage for a brand-name drug.

79. The rebate owed by a drug manufacturer on a generic (N) drug is 13% of the Average Manufacturer Price (“AMP”).

80. For brand-name (S or I) drugs, on the other hand, the rebate owed by the manufacturer is no less than 23.1% of the AMP (but no more than 50% of the AMP).

81. When the EpiPen was first reported to CMS, it was correctly classified by Meridian as an S drug because it was approved under a NDA and had no therapeutic equivalents.

IV. Mylan’s Reporting Obligations as a Public Company

82. Under the federal securities laws and the regulations and guidance promulgated by the SEC pursuant to those laws, companies whose stock is publicly traded in the U.S. – such as Mylan – have important reporting and disclosure obligations.

83. Public companies are required to file with the SEC certain disclosure documents containing comprehensive information about their business operations and their financial condition. Investors rely on the accuracy and transparency of these disclosures when determining whether to invest.

84. The following table sets forth the periodic filings that Mylan (or its predecessor) made with the SEC during the relevant period, the date they were filed with the SEC, which of the Defendants signed those filings, and how they will referred to throughout this Complaint:

Description of Filing	Date of Filing	Defendant Signatories	Abbreviation
Form 10-K for year ended December 31, 2013	February 27, 2014	Bresch Sheehan Malik	“2013 Annual Report”
Form 8-K and Press Release	March 2, 2015	Sheehan	“2014 Annual Earnings Release”
Form 10-K for year ended December 31, 2014	March 2, 2015	Bresch Sheehan Malik	“2014 Annual Report”

Description of Filing	Date of Filing	Defendant Signatories	Abbreviation
Form 8-K and Press Release	May 5, 2015	Sheehan	“2015 First Quarter Earnings Release”
Form 10-Q for quarter ended March 31, 2015	May 7, 2015	Bresch Sheehan	“2015 First Quarter Report”
Form 8-K and Press Release	August 6, 2015	Sheehan	“2015 Second Quarter Earnings Release”
Form 10-Q for quarter ended June 30, 2015	August 6, 2015	Bresch Sheehan	“2015 Second Quarter Report”
Form 8-K and Press Release	October 30, 2015	Sheehan	“2015 Third Quarter Earnings Release”
Form 10-Q for quarter ended September 30, 2015	October 30, 2015	Bresch Sheehan	“2015 Third Quarter Report”
Form 8-K and Press Release	February 10, 2016	Sheehan	“2015 Annual Earnings Release”
Form 10-K for year ended December 31, 2015	February 16, 2016	Bresch Sheehan Campbell Malik	“2015 Annual Report”
Form 8-K and Press Release	May 3, 2016	Campbell	“2016 First Quarter Earnings Release”
Form 10-Q for quarter ended March 31, 2016	May 3, 2016	Bresch Campbell	“2016 First Quarter Report”
Form 8-K and Press Release	August 9, 2016	Parks	“2016 Second Quarter Earnings Release”
Form 10-Q for quarter ended June 30, 2016	August 9, 2016	Bresch Parks	“2016 Second Quarter Report”

85. As a publicly traded corporation with significant operations in the U.S., Mylan is required to prepare its financial statements in accordance with United States Generally Accepted Accounting Principles (“U.S. GAAP”) in order for those financial statements not to be deemed

misleading and inaccurate. U.S. GAAP is a set of rules and standards that are designed to ensure uniform financial reporting.

86. In addition to complying with U.S. GAAP, public companies are required to follow the standards developed by the SEC governing what information must be disclosed in financial statements and other public filings.

87. Public companies such as Mylan are required to maintain effective disclosure controls and procedures to ensure compliance with their SEC reporting obligations. An issuer's top-ranking executives must be involving in creating and designing these controls, and also must personally guarantee their effectiveness.

88. The Committee of Sponsoring Organizations of the Treadway Commission's *Internal Control – Integrated Framework* defines internal control as “a process, effected by an entity's board of directors, management, and other personnel, designed to provide reasonable assurance regarding the achievement of objectives relating to operations, reporting and compliance.” With respect to the reporting and compliance aspects of this definition, the *Integrated Framework* specifically states that “[w]hen internal control is determined to be effective, senior management and the board of directors have reasonable assurance [that] . . . the organization prepares reports in conformity with applicable laws, rules and regulations, and standards established by legislators, regulators, and standard setters, . . . [and that] the organization complies with applicable laws, rules and regulations.” See The Committee of Sponsoring Organizations of the Treadway Commission's *Internal Control – Integrated Framework* § 3 (“Requirements for Effective Internal Control”).

89. Section 404 of the Sarbanes-Oxley Act of 2002 (“SOX”) requires public companies to publish information in their annual reports concerning the scope and adequacy of

their internal control structure and procedures for financial reporting, and also to assess the effectiveness of such internal controls and procedures. When management identifies a control deficiency, it cannot claim that its internal controls are effective if the control deficiency is deemed to be a material weakness.

90. Section 302 of SOX requires a public company's chief executive officer and chief financial officer to provide certifications concerning their review of, and disclosure of information about, the company's internal controls. Specifically, pursuant to rules promulgated by the SEC to implement Section 302 of SOX, the CEO and CFO are required to certify in each periodic report that:

- he or she has reviewed the report;
- based on his or her knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by the report;
- based on his or her knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in the report;
- he or she and the other certifying officers:
 - are responsible for establishing and maintaining "disclosure controls and procedures" [i.e., controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports filed or submitted by it under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms] for the issuer;
 - have designed such disclosure controls and procedures to ensure that material information is made known to them, particularly during the period in which the periodic report is being prepared;

- have evaluated the effectiveness of the issuer's disclosure controls and procedures as of a date within 90 days prior to the filing date of the report; and
- have presented in the report their conclusions about the effectiveness of the disclosure controls and procedures based on the required evaluation as of that date;
- he or she and the other certifying officers have disclosed to the issuer's auditors and to the audit committee of the board of directors (or persons fulfilling the equivalent function):
 - all significant deficiencies in the design or operation of internal controls which could adversely affect the issuer's ability to record, process, summarize and report financial data and have identified for the issuer's auditors any material weaknesses in internal controls; and
 - any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal controls; and
- he or she and the other certifying officers have indicated in the report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Certification of Disclosure in Companies' Quarterly and Annual Reports, Exchange Act Release 46427, § II.A (Sept. 9, 2002) (footnotes omitted).

91. The following table shows which Defendant provided these internal control certifications with Mylan's SEC filings during the relevant period:

SEC Filing	CEO Certification	CFO Certification
2013 Annual Report	Bresch	Sheehan
2014 Annual Report	Bresch	Sheehan
2015 First Quarter Report	Bresch	Sheehan
2015 Second Quarter Report	Bresch	Sheehan

SEC Filing	CEO Certification	CFO Certification
2015 Third Quarter Report	Bresch	Sheehan
2015 Annual Report	Bresch	Sheehan
2016 First Quarter Report	Bresch	Campbell
2016 Second Quarter Report	Bresch	Parks

92. As explained in greater detail below, throughout the relevant period Mylan represented to investors that it was complying with these important public reporting obligations by timely disclosing truthful material facts about its business and maintaining effective internal controls. However, unbeknownst to the market, between 2014 and 2016, Defendants made material misrepresentations and failed to disclose material information that they had a duty to disclose, in order to artificially inflate the price of Mylan's common stock. Defendants did this by: (1) purporting to provide explanations in Mylan's SEC reports about how the EpiPen contributed to Mylan's financial performance, but without apprising the market that these figures were grossly inflated because Mylan had not paid hundreds of millions of dollars in rebates that it owed Medicaid as a result of its intentional misclassification of the EpiPen under the MDRP; (2) misleading the investing public that Mylan was paying the correct rebate amount to Medicaid for the EpiPen when, in fact, Mylan was drastically underpaying Medicaid the rebates it owed on EpiPen sales funded by U.S. taxpayers; (3) lying to investors about their knowledge of the EpiPen misclassification; (4) cautioning the market that improper classification of the EpiPen could lead to regulatory scrutiny without informing investors that Mylan was already under investigation for misclassifying the EpiPen; (5) falsely asserting that the market for the EpiPen was very competitive without disclosing the anticompetitive conduct in which Mylan was engaging with respect to the EpiPen; and (6) incorrectly certifying that Mylan had effective

disclosure controls and procedures when, in fact, such internal controls were virtually non-existent.

V. Mylan Misleads Investors about the EpiPen

A. Mylan's Misclassification of the EpiPen to Reduce the Medicaid Rebate

93. Between the time when it acquired the rights to market and distribute the EpiPen in 2007 and 2016, but unbeknownst to the investing public, Mylan blatantly misclassified the EpiPen to CMS under the MDRP as a non-innovator multiple source "N" drug.

94. Mylan had absolutely no basis for classifying the EpiPen as a N drug.

95. As described above, both the law and CMS's directions to manufacturers are clear that a drug approved by the FDA under a NDA (as opposed to under an ANDA), must be classified as either a single source "S" drug or an innovator multiple source "I" drug.

96. As Defendants were well aware, EpiPen was approved by the FDA for marketing in the United States under a NDA (NDA019430), and not under an ANDA.

97. Furthermore, during the relevant period, the EpiPen had no therapeutic equivalent, which means that it must be classified as an "S" drug, and not as a "N" drug.

98. In addition, the EpiPen has patent protection until 2025. CMS has been clear that drugs with patent protection cannot be classified as N drugs.

99. The reason for Defendants' misclassification of the EpiPen is simple: by doing so, they drastically reduced the amount of the rebate that Mylan owed to Medicaid under the MDRP. This had the effect of inflating Mylan's reported revenues and profits.

100. Defendants' covert misclassification of the EpiPen to Medicaid as a generic drug was antithetical to how they publicly marketed the EpiPen.

101. After Mylan acquired the rights to sell the EpiPen, it launched a massive marketing campaign to make the EpiPen a household name, where adults and parents of children

suffering from life-threatening food allergies would consider EpiPen to be an essential instrument that they must carry with them at all times.

102. These efforts were successful. Through aggressive marketing and anticompetitive conduct (described below), Mylan increased EpiPen's share of the epinephrine auto-injector market to almost 100%. This, in turn, allowed Mylan to exponentially hike up the price of the EpiPen.

103. Thus, in classifying the EpiPen as a generic drug for purposes of the MDRP, but marketing the EpiPen as an unrivaled brand-name drug, Defendants were trying to have their cake and eat it too. Defendants wanted to sell the EpiPen for the high price of a brand-name drug. But they also wanted to rebate Medicaid the smallest amount possible, so they misclassified the EpiPen as a generic drug for purposes of the MDRP. As a result, Defendants profited at the expense of the U.S. taxpayer, while Medicaid had less funds available to it to provide healthcare to needy families.

104. CMS repeatedly informed Mylan that its classification of the EpiPen as a N drug was incorrect. On October 5, 2016, Andrew Slavitt, the Acting Administrator of CMS, sent a letter to the Senate Finance Committee in which he stated:

The Center for Medicaid and CHIP Services in *CMS has, on multiple occasions*, provided guidance to the industry and Mylan on the proper classification of drugs and has *expressly told Mylan that the product is incorrectly classified*.

105. As the Court recognized in ruling in Defendants' first motion to dismiss in the Class Action, CMS likely started informing Mylan of the misclassification after CMS was informed by the Office of Inspector General for the United States Department of Health and Human Services ("Office of Inspector General") that Mylan was misclassifying the EpiPen as a generic drug.

106. The United States Department of Justice (“DOJ”) also opened an investigation into Mylan’s classification of the EpiPen. In November 2014, Mylan received a subpoena from the DOJ related to the classification of the EpiPen for purposes of the MDRP. Mylan did not disclose the existence of this investigation until two years later, when it stated that it had “complied with various information requests received from the DOJ pursuant to the subpoena” and had subsequently settled with the DOJ.

107. The Office of Inspector General recently determined that Mylan’s misclassification of the EpiPen over a 10-year period cost Medicaid a whopping \$1,270,000,000.

B. Mylan’s Anticompetitive Conduct with Respect to the EpiPen

108. In addition to its misclassification of the EpiPen to reduce its payments to Medicaid, Mylan also engaged in anticompetitive conduct to prevent competition for the EpiPen.

109. During the relevant time period, Mylan controlled more than 90% of the market for epinephrine auto-injectors. This dominance of the market allowed Mylan to steadily increase the price of the EpiPen.

110. To retain its monopoly over the epinephrine auto-injector market, Mylan offered higher rebates and discounts to the PBMs in return for the EpiPen receiving exclusive or preferred placement on the PBM’s formularies.

111. For example, in 2013, Sanofi-Aventis U.S. LLC (“Sanofi”) attempted to introduce a competitor to the EpiPen, called the Auvi-Q. The Auvi-Q was a serious threat to Mylan’s control of the market. Sanofi offered the Auvi-Q at around the same price as the EpiPen, but the Auvi-Q had certain advantages over the EpiPen, including the ability to provide a recorded voice instruction on how to administer the Auvi-Q.

112. Mylan immediately took steps to block the Auvi-Q from drug formularies by offering large rebates to the PBMs of 30% or higher in return for the PBMs removing the Auvi-

Q from the formularies. The rebates offered to the PBMs were significantly higher than any rebates that Mylan had historically offered PBMs to include EpiPen on formularies. To fund the rebates, Mylan increased the price of the EpiPen.

113. Because Sanofi did not have a large enough share of the epinephrine auto-injector market to offer comparable discounts to the PBMs, Mylan was able to defeat Sanofi from effectively competing with the EpiPen.

114. Mylan successfully blocked Sanofi from accessing a large portion of the epinephrine auto-injector market.

C. Mylan's Misrepresentations to Investors Regarding the EpiPen

115. During the relevant period, Defendants made numerous statements to the market about the EpiPen that were materially false or that omitted to state material facts necessary to make their statements not misleading.

116. First, Mylan purported to provide explanations in its SEC reports about how the EpiPen contributed to its financial performance. However, in making these statements concerning the causes and sources of Mylan's financial performance, Defendants failed to apprise the market that these figures were grossly inflated because Mylan had not paid hundreds of millions of dollars in rebates that it owed Medicaid as a result of its intentional misclassification of the EpiPen under the MDRP. Having purported to set forth the basis for Mylan's reported financials, Defendants had a duty to provide complete information to the market about how the misclassification of the EpiPen was inflating Mylan's financial results.

117. Second, Defendants misled the investing public that they were paying the correct rebate amount to Medicaid for the EpiPen. Specifically, Defendants set forth in Mylan's periodic reports filed with the SEC the rebate rates "required" by Congress and the CMS, *i.e.*, that a drug marketed under an ANDA owed a Medicaid rebate of 13%, whereas a drug marketed

under a NDA required a rebate of at least 23%. In making this statement, Defendants failed to inform investors that even though the EpiPen was marketed under a NDA, they had classified it as a N drug and were only paying Medicaid a rebate of 13%.

118. Third, Defendants misled investors about their knowledge of the EpiPen misclassification. In discussing the risks purportedly associated with MDRP classification decisions, Defendants warned that their rebate calculations could be wrong. In doing so, Defendants implied that their rebate calculations could be correct, without disclosing that they were deliberately misclassifying the EpiPen as a generic drug.

119. Fourth, Defendants improperly cautioned the market that improper classification of the EpiPen could lead to regulatory scrutiny without informing investors that they were already under investigation for misclassifying the EpiPen. Specifically, Defendants failed to disclose that in November 2014 Mylan received a subpoena from the DOJ as part of an investigation about the classification of the EpiPen. Moreover, Defendants failed to apprise the market that CMS had expressly informed Mylan on multiple occasions that its classification was incorrect.

120. Finally, Defendants misleadingly told investors that the market for the EpiPen was very competitive. These statements were false and failed to disclose the anticompetitive conduct in which Mylan was engaging with respect to the EpiPen.

VI. Mylan's Lack of Disclosure Controls

121. Defendants were able to mislead the investing public because Mylan's control environment was fundamentally flawed.

122. Unbeknownst to investors at the time, Mylan's disclosure controls and procedures suffered from a host of material weaknesses.

123. During the relevant period, Mylan did not have effective disclosure controls and procedures in place to assure that Defendants could not mislead investors about the misclassification of the EpiPen and Mylan's anticompetitive conduct with respect to the EpiPen.

124. Defendants knew about, or recklessly disregarded, the material weaknesses in Mylan's disclosure controls and procedures, but falsely stated to the market that they had designed and implemented a system of effective disclosure controls and procedures.

125. The material weaknesses in Mylan's control environment were highlighted by its entry into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General as part of Mylan's settlement with the DOJ over its EpiPen misclassification.

126. The CIA required Mylan to make certain enhancements to its Corporate Compliance Program and to implement certain reporting requirements. The CIA required Mylan to, among other things:

- (a) Appoint a senior member of management as an independent Compliance Officer who reports directly to the CEO. The Compliance Officer was to be responsible for "developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements"; "making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Mylan Inc."; and "monitoring the day-to-day compliance activities engaged in by Mylan as well as for any reporting obligations created under this CIA."
- (b) Create a Compliance Committee comprised of the Compliance Officer and members of senior management who have responsibility for, among others, the audit and operations departments.
- (c) Pass an annual Board resolution that states the following: "The Board of Directors (or a committee thereof) has made a reasonable inquiry into the operation of Mylan's Compliance Program during the preceding twelve-month period including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Mylan has implemented an effective Compliance

Program to meet Federal health care program requirements and the obligations of the Corporate Integrity Agreement.”

- (d) Have Mylan’s CFO, Head of Commercial Finance – North America, Head of Government Reporting, Head of Finance, Global Integrated Services – North America, and Director, Accounts Receivable sign annual certifications that their respective business units are compliant with applicable healthcare program requirements and with the obligations of the CIA.
- (e) Develop and implement written policies and procedures regarding the operation of its Compliance Program. The CIA requires that, “[a]t a minimum, the Policies and Procedures shall address appropriate ways to conduct Government Pricing Functions in compliance with all applicable Federal health care program requirements. This includes (a) gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare & Medicaid Services (CMS) and/or the State Medicaid Programs in connection with the Medicaid Drug Rebate Program, the Medicare program, and as otherwise required by Federal or state government requirements and directives; and (b) the appropriate classification of drugs as Single Source, Innovator Multiple Source, or Non-Innovator Multiple Source drugs for purposes of the Medicaid Drug Rebate Program.”
- (f) Develop a written training plan “that outlines the steps Mylan will take to ensure that: (a) all Covered Persons receive adequate training regarding Mylan’s CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute, and (b) all Relevant Covered Persons receive adequate training regarding: (i) Mylan’s systems and processes relating to Government Pricing Functions; (ii) all applicable Federal health care program requirements relating to Government Pricing Functions; and (iii) Mylan’s systems for gathering relevant data and calculating, verifying, and reporting information to CMS and/or the State Medicaid Programs for purposes of the Medicaid Drug Rebate Program, the Medicare Program, or any other Federal or state government price reporting requirement.”
- (g) Subject each member of the Board to at least two hours of training that addresses “the corporate governance responsibilities of board members and the responsibilities of board members with respect to review and oversight of the Compliance Program.”
- (h) Engage an Independent Review Organization to report on Mylan’s classification of drugs under the MDRP.

- (i) Develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the drugs that are paid for by Medicaid.
- (j) Establish a disclosure program that “includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual’s chain of command any identified issues or questions associated with Mylan’s policies, conduct, practices, or procedures with respect to a Federal health care program requirement believed by the individual to be a potential violation of criminal, civil, or administrative law.” “Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information to determine whether a further review should be conducted.”
- (k) Provide written notice to the Office of Inspector General – within thirty days of discovery – “of any ongoing investigation or legal proceeding known to Mylan conducted or brought by a governmental entity or its agents involving an allegation that Mylan has committed a crime or has engaged in fraudulent activities.”
- (l) Provide written notice to the Office of Inspector General – within thirty days of determining that a “Reportable Event” has occurred – of “a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program requirements for which penalties or exclusion may be authorized.”

127. Mylan’s agreement to undertake these improvements to its internal controls highlights the significant deficiencies in its disclosure controls and procedures that needed to be addressed as of the end of 2016 (when Mylan entered into the CIA). The fact that Mylan had to implement these measures demonstrates the falsity of Defendants’ prior certifications concerning the purported effectiveness of Mylan’s disclosure controls and procedures.

VII. Mylan's Misclassification of the EpiPen, Its Anticompetitive Conduct Regarding the EpiPen, and Its Lack of Effective Disclosure Controls and Procedures Is Exposed

128. During the second half of 2016, Mylan's misclassification of the EpiPen and anticompetitive conduct began to unravel.

129. On August 22, 2016, Senator Amy Klobuchar, the top Democrat on the Senate Judiciary Committee's Antitrust Subcommittee, released a statement calling for the Federal Trade Commission ("FTC") to investigate whether Mylan had violated the antitrust laws in selling the EpiPen. Specifically, Senator Klobuchar pleaded with the FTC to probe whether Mylan "engaged in activity, *such as using incentives or exclusionary contracts with insurers, distributors, or pharmacies, to deny an alternative product access to the market.*"

130. That same day, Senator Chuck Grassley, the Chairman of the Senate Judiciary Committee, sent a letter to Defendant Bresch, asking that Mylan provide information to Congress concerning its pricing practices with respect to the EpiPen.

131. This government scrutiny over the EpiPen continued over the next two days. On August 23, 2016, Bloomberg reported that the price of Mylan's stock was continuing to drop because U.S. senators were trying to understand how Mylan had been able to exponentially raise the cost of the EpiPen.

132. On August 24, 2016, Senators Susan Collins and Clair McCaskill, on behalf of Senate Special Committee on Aging, sent a letter to Defendant Bresch asking Mylan to provide "any analysis used by Mylan relating to the pricing or market share of EpiPen since 2007."

133. On September 2, 2016, Senator Ron Wyden and Representative Frank Pallone Jr. sent a letter to HHS Secretary Sylvia Mathews Burwell, saying that Medicaid may have been grossly overpaying for the EpiPen due to a misclassification by Mylan of the EpiPen as a generic drug for purposes of the MDRP. According to Senator Wyden and Representative Pallone,

Mylan may have been incorrectly designating the EpiPen as a generic in the Medicaid program for years, despite being considered a brand-name drug by the FDA. According to the letter, this would mean Mylan had been “vastly underpaying rebates owed to Medicaid for the EpiPen for years.” They concluded the letter by HHS for more information about the EpiPen’s classification under the MDRP.

134. Mylan immediately denied any misclassification of the EpiPen. In a statement released on September 2, 2016, as the market reacted to the disclosures in Senator Wyden and Representative Pallone’s letter, a Mylan spokeswoman, Nina Devlin, said “Mylan has complied with all laws and regulations regarding the Medicaid rebate classification” of the EpiPen, and that the EpiPen meets the definition of a N drug under the law.

135. On October 5, 2016, CMS submitted its response to Senator Wyden and Representative Pallone’s information request, which Bloomberg alerted investors to after the markets closed in an article titled, “Mylan Overcharged U.S. on EpiPen for Years, U.S. Says.” The CMS letter stated that, from 2011 to 2015, net Medicaid spending on the EpiPen was approximately \$797 million, which reflected a rebate of only 13% paid by Mylan. According to the letter, Medicaid should have been getting a larger discount of at least 23.1% because the EpiPen was approved under a NDA, has patent protection, and did not have any FDA-approved therapeutic equivalents. Further, CMS stated that it had, “on multiple occasions,” “expressly told Mylan that the product is incorrectly classified.” CMS could not tell Congress at that time exactly how much Mylan had overcharged Medicaid.

136. However, Mylan continued to publicly deny that it had misclassified the EpiPen. In response to this letter, Devlin said in an e-mail to Bloomberg that Mylan had previously stated that the EpiPen meets the definition of a N drug. According to Devlin, Mylan’s classification of

the EpiPen as a N drug “is consistent with longstanding written guidance from the federal government.”

137. On October 7, 2016, prior to the opening of the markets, Senator Klobuchar released a statement commenting on a reported \$465 million settlement between the DOJ and Mylan “over the misclassification of the EpiPen.”

138. Later that morning, the *Washington Examiner* released an article titled, “EpiPen maker to pay \$465 million for overcharging feds.” The article quoted Defendant Bresch as saying, “[t]his agreement is another important step in Mylan’s efforts to move forward and bring resolution to all EpiPen Auto-Injector related matters.” The article also revealed that Mylan did not admit wrongdoing in the settlement. Later that day, Mylan issued its official press release addressing the settlement.

139. On October 11, 2016, after the close of trading, CNBC reported that Mylan’s settlement with the DOJ had a “\$120 million question attached to it” relating to a six-month grace period during when it was unclear how much in rebates Mylan would owe.

DEFENDANTS’ FALSE AND MISLEADING STATEMENTS AND OMISSIONS

I. Defendants Make Misleading Statements Explaining Mylan’s Financial Performance

140. During the relevant period, Mylan reported its financial results in quarterly and annual filings with the SEC. Around the time that it filed the applicable Form 10-K or Form 10-Q with the SEC, Mylan also filed an Earnings Release with the SEC on Form 8-K, in which Defendants explained the causes and sources of Mylan’s financial performance for the applicable period. In these filings, Defendants purported to provide explanations about how the EpiPen contributed to Mylan’s financial performance.

141. In its 2014 Annual Earnings Release, Mylan stated as follows:

Specialty Segment Revenue

Specialty segment reported third party net sales of \$1.19 billion for the year, an increase of 21% when compared to the prior year. ***The increase was due to higher net sales of the EpiPen® Auto-Injector driven by increased volume and favorable pricing. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector and, in 2014, became Mylan's first product to reach \$1 billion in annual net sales.***

Total Gross Profit

Adjusted gross profit was \$4.05 billion and adjusted gross margins were 52% for the year as compared to adjusted gross profit of \$3.46 billion and adjusted gross margins of 50% in the comparable prior year. ***Strong adjusted gross margins were the result of new products and growth in the EpiPen® Auto-Injector.*** GAAP gross profit for the year was \$3.53 billion and GAAP gross margins were 46% as compared to GAAP gross profit of \$3.04 billion and GAAP gross margins of 44% in the comparable prior year.

Total Profitability

Adjusted earnings from operations for the year were \$2.07 billion, up 21% from the comparable prior year. SG&A expense increased from the prior year period as a result of ***increased selling and marketing investments related to the EpiPen® Auto-Injector franchise*** and increased infrastructure costs including legal and marketing costs in the North American region to support anticipated new product launches. R&D expense also increased as we continued to invest in our biologics and respiratory growth platforms. GAAP earnings from operations were \$1.35 billion for the year, an increase of 19% from the comparable prior year.

142. In its 2015 First Quarter Earnings Release, Mylan stated as follows:

Specialty segment reported third party net sales of \$211.1 million for the quarter, an increase of 8% when compared to the prior year period. ***This increase was primarily due to higher net sales of the EpiPen® Auto-Injector driven by increased volume.***

143. In its 2015 Second Quarter Earnings Release, Mylan stated as follows:

Specialty segment reported third party net sales of \$301.9 million for the quarter, an increase of 5% when compared to the prior year period. ***This increase was primarily due to growth across the***

segment, including higher volumes of the EpiPen® Auto-Injector.

144. In its 2015 Third Quarter Earnings Release, Mylan stated as follows:

Specialty segment reported third party net sales of \$437.8 million for the quarter, a decrease of 5% when compared to the prior year period. *This decrease was primarily due to a lower average net selling price for the EpiPen® Auto-Injector as a result of competitive market conditions.*

145. In its 2015 Annual Earnings Release, Mylan stated as follows:

Specialty segment reported third party net sales were \$254.1 million for the quarter, an increase of 5% when compared to the prior year period. *This increase was primarily due to higher net sales of the EpiPen® Auto-Injector due to higher volumes, but with the same net payor pricing dynamics that existed throughout 2015.*

...

Specialty segment reported third party net sales of \$1.20 billion for the year, an increase of 1% when compared to the prior year. *This increase was partially due to higher volumes of the EpiPen® Auto-Injector, which was offset by lower pricing. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector and as a global franchise reached \$1 billion in annual net sales for the second year in a row.* In addition, sales of the Perforomist® Inhalation Solution and ULTIVA® increased by double digit percentage points from the prior year.

146. In its 2016 First Quarter Earnings Release, Mylan stated as follows:

Specialty segment reported third party net sales were \$247.9 million for the quarter, an increase of 17% when compared to the prior year period. *This increase was primarily the result of higher volumes of the EpiPen® Auto-Injector and higher sales of the Perforomist® Inhalation Solution.*

147. In its 2016 Second Quarter Earnings Release, Mylan stated as follows:

Specialty segment third party net sales were \$402.5 million for the quarter, an increase of 33% when compared to the prior year period. *This increase was primarily the result of higher unit volumes and the realization of the benefits of customer contract negotiations over the last several quarters related to the EpiPen®*

Auto-Injector, and higher sales of the Perforomist® Inhalation Solution and ULTIVA®.

...

Specialty segment third party net sales were \$650.4 million for the six months ended June 30, 2016, an increase of 27% when compared to the prior year period. ***This increase was primarily the result of higher unit volumes and the realization of the benefits of customer contract negotiations over the last several quarters related to the EpiPen® Auto-Injector***, and higher sales of the Perforomist® Inhalation Solution and ULTIVA®.

148. The statements set forth above in paragraphs 140 through 147 were materially false and misleading, and omitted to state material facts, because Defendants failed to apprise the market that these figures were grossly inflated because Mylan had not paid hundreds of millions of dollars in rebates that it owed Medicaid as a result of its intentional misclassification of the EpiPen under the MDRP. Having purported to set forth the basis Mylan's reported financials, Defendants had a duty to provide complete information to the market about how the misclassification of the EpiPen was inflating Mylan's financial results.

149. Indeed, as the Court found in ruling on Defendants' first motion to dismiss in the Class Action:

[A]ttributing EpiPen's strength to "favorable pricing and volume" . . . may have been misleading in the absence of an additional statement disclosing that the EpiPen's strength was *also* due to anticompetitive agreements and knowingly miscalculated Medicaid rebates. . . . Mylan's repeated use of casual language such as "as a result of," "primarily the result of," "driven by," and "due to" exacerbates the problem. . . .

...

[T]he Court concludes that Mylan's statements explaining income were misleading because Mylan failed to disclose that "Mylan's net income and revenue were inflated because Mylan knowingly had misclassified the EpiPen" . . . and that "Mylan's income and revenue were inflated as a result of Mylan's anticompetitive activity"

II. Defendants Mislead Investors about the Rebates Mylan Was Paying Medicaid

150. In each of Mylan's annual reports during the relevant period, Defendants made statements about how Medicaid rebates are calculated under the MDRP.

151. In Mylan's 2013 Annual Report, Defendants stated:

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and brand pharmaceuticals effective January 1, 2010. *The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs*, up from 11% for periods prior to 2010. *Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.* We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

152. In Mylan's 2014 Annual Report, Defendants stated:

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages effective January 1, 2010. *The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed non-innovator products*, up from 11% for periods prior to 2010. *Sales of Medicaid-reimbursed innovator or single-source products require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.* We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

153. In Mylan's 2015 Annual Report, Defendants stated:

Medicaid, a U.S. federal healthcare program, requires pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. *Sales of Medicaid-reimbursed non-innovator products require manufacturers to rebate 13% of the average manufacturer's price and, effective 2017, adjusted by the Consumer Price Index-Urban (the "CPI-U") based on certain data. Sales of the Medicaid-reimbursed innovator or single-source products require manufactures to the rebate the greater of approximately 23% of the average manufacturer's price or the difference between the average manufacturer's price and the best price adjusted by the CPI-U based on certain data.* We believe that federal or state governments will continue to enact measures aimed at reducing the cost of drugs to the public.

154. The statements set forth above in paragraphs 150 through 153 were materially misleading, and omitted to state material facts, because Defendants misled the investing public that they were paying the correct rebate amount to Medicaid for the EpiPen. Specifically, Defendants failed to inform investors that even though the EpiPen was marketed under a NDA, patent protected, and had no FDA-approved therapeutic equivalents, they had classified it as a N drug and were only paying Medicaid a rebate of 13%.

155. Indeed, as the Court found in ruling on Defendants' first motion to dismiss in the Class Action:

In its [2013 Annual Report], Mylan stated a simple rule: *If ANDA, then 13%*. This statement is true, but was made misleading by Mylan's failure to disclose that this formula was untrue in the case of the EpiPen, which was marketed under a NDA but rebated at 13%. Mylan's [2014 Annual Report and 2015 Annual Report] are less blatantly misleading, stating instead: *If N drug, then 13%*. Mylan did, in fact, classify EpiPen as a N drug and rebate at 13%. However, read in the context of Mylan's previous [2013 Annual Report], a reasonable investor would likely infer that if ANDA-marketed drugs are rebated at 13%, and N drugs are marketed at 13%, then N drugs are those drugs that are marketed under ANDAs. In other words: If ANDA equals 13%, and N drug equals 13%, then ANDA-marketed drugs and N drugs are equivalents.

That was not true in the case of the EpiPen, which was marketed under a NDA but rebated at the N drug rate. Consequently, each of Mylan's Form 10-K Annual Reports contained statements that, absent a clear statement of the EpiPen rebate rate, could have misled a reasonable investor as to the rate at which Mylan was rebating the EpiPen.

III. Defendants Misrepresent Their Knowledge of Mylan's Misclassification of the EpiPen

156. In discussing the risks purportedly associated with MDRP classification decisions, Defendants warned that their rebate calculations could be wrong.

157. In each of Mylan's annual reports filed with the SEC during the relevant period, Defendants stated that Mylan's calculations of the Medicaid rebates were subject to "risk of errors." For example, Mylan's 2014 Annual Report stated:

Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal health care programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, *these calculations are subject to risk of errors* and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences.

158. Defendants made substantially similar representations about the "risk of errors" in Mylan's 2013 Annual Report and its 2015 Annual Report.

159. The statements set forth above in paragraphs 156 through 158 were materially misleading, and omitted to state material facts, because Defendants implied that their rebate calculations could be correct, without disclosing that they were deliberately misclassifying the EpiPen as a generic drug.

160. Indeed, as the Court found in ruling on Defendants’ first motion to dismiss in the Class Action, the “only reasonable inference an investor could have drawn” from Defendants’ statements discussing the risks purportedly associated with MDRP classification decisions was:

[t]hat, at the time of the disclosure, Mylan did not *affirmatively know* that the EpiPen was misclassified. While warning that the rebate calculation *could be wrong* does not imply that the rebate calculation is correct, such a warning does imply that the rebate calculation *could also be correct*. If Mylan knew for certain that the EpiPen was misclassified, then warning about the “risk of errors” could have mislead a reasonable investor as to Mylan’s then-existing knowledge.

IV. Defendants Falsely Lead Investors to Believe that the Government Had Not Taken Any Adverse Actions against Mylan Regarding Its Misclassification of the EpiPen

161. Defendants cautioned the market that improper classification of the EpiPen could lead to lead to regulatory scrutiny.

162. In each of Mylan’s annual reports filed during the relevant period, Defendants stated that Mylan could be subjected to investigation and that a governmental authority could take a position contrary to Mylan in calculating Medicaid rebates for the EpiPen. For example, in Mylan’s 2014 Annual Report, Defendants stated:

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN FEDERAL HEALTH CARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ***ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.***

...

Any governmental agencies or authorities that have commenced, or may commence, an investigation of Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of

anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal health care programs, including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, *should there be ambiguity with regard to how to properly calculate and report payments - and even in the absence of any such ambiguity - a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions.*

163. Defendants made substantially similar representations in Mylan's 2013 Annual Report and its 2015 Annual Report.

164. The statements set forth above in paragraphs 161 through 163 were materially misleading, and omitted to state material facts, because Defendants failed to inform investors that they were already under investigation for misclassifying the EpiPen. Specifically, Defendants failed to disclose that in November 2014 Mylan received a subpoena from the DOJ as part of an investigation about the classification of the EpiPen. Moreover, Defendants failed to apprise the market that CMS had expressly informed Mylan on multiple occasions that its classification was incorrect.

165. Indeed, as the Court found in ruling on Defendants' first motion to dismiss in the Class Action:

Mylan's statements regarding the risk that "a governmental authority may take a . . . contrary" position and the risk that it "could [be] subject[ed] . . . to investigation" both fall on the potentially misleading side of the line. A reasonable investor could have concluded from Mylan's statement that although the government "may" disagree with Mylan, and "could" open an investigation, such unfavorable events had not yet occurred. In this context, "to warn that the untoward may occur when the event is contingent is prudent; to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit." *In re Van der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 400 (S.D.N.Y. 2005) (quoting *Voit v. Wonderware Corp.*, 977 F. Supp. 363, 371 (E.D. Pa. 1997))

V. **Defendants Misleadingly Tell Investors that the Market for the EpiPen Was Competitive**

166. Defendants made numerous statements in Mylan's SEC filings that the market for the EpiPen was very competitive.

167. In each of Mylan's 2013 Annual Report, 2014 Annual Report, and 2015 Annual Report, Defendants made statements about Mylan's competition. For example, in the 2014 Annual Report, Mylan stated:

Competition

Our *primary competitors* include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, *key competitors* are generally other branded drug companies *that compete based on their clinical characteristics and benefits*.

Competitive factors in the major markets in which we participate can be summarized as follows:

United States. The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. *Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.*

The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. *To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products.* With regard to our Specialty segment business, *significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.*

Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents

expire. Further regulatory approval is not required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. ***Related to our Specialty segment business, our competitors include branded manufacturers who offer products for the treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.***

168. Defendants made substantially similar representations about Mylan's purported "competition" for the EpiPen in Mylan's 2013 Annual Report and its 2015 Annual Report.

169. The statements set forth above in paragraphs 166 through 168 were materially false and misleading, and omitted to state material facts, because Defendants failed to disclose the anticompetitive conduct in which Mylan was engaging with respect to the EpiPen. For example, Mylan successfully blocked Sanofi from accessing a large portion of the epinephrine auto-injector market by incentivizing PBMs to exclude Sanofi's epinephrine auto-injector, the Auvi-Q, from drug formularies controlled by the PBMs. Mylan did this by offering large rebates to the PBMs of 30% or higher in return for the PBMs removing the Auvi-Q from the formularies. Because Sanofi did not have a large enough share of the epinephrine auto-injector market to offer comparable discounts to the PBMs, Mylan was able to defeat Sanofi from effectively competing with the EpiPen. Thus, Defendants' representations of Mylan facing competition for the EpiPen were materially false and misleading.

VI. Defendants Misrepresent the Effectiveness of Mylan's Disclosure Controls and Procedures

170. Defendants repeatedly certified that they had established effective disclosure controls and procedures for Mylan.

171. For example, in its 2013 Annual Report, Mylan disclosed:

An evaluation was performed under the supervision and with the participation of the Company's management, including the

Principal Executive Officer and the Principal Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of December 31, 2013. Based upon that evaluation, *the Principal Executive Officer and the Principal Financial Officer concluded that the Company's disclosure controls and procedures were effective.*

172. Mylan made substantially similar internal control disclosures in its 2014 Annual Report, 2015 First Quarter Report, 2015 Second Quarter Report, 2015 Third Quarter Report, 2015 Annual Report, 2016 First Quarter Report, and 2016 Second Quarter Report, affirmatively stating that Mylan had effective disclosure controls and procedures during the relevant period, and that there had been no material changes in Mylan's internal controls since the prior period.

173. Along with the 2013 Annual Report, Defendants Bresch and Sheehan provided a certification, pursuant to Section 302 of SOX, concerning Mylan's internal controls. Each of Bresch and Sheehan stated:

1. I have reviewed this Form 10-K of Mylan, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- ...
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) . . . for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

...

- c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation

174. Defendants Bresch and Sheehan provided substantially identical certifications pursuant to Section 302 of SOX for the relevant periods with Mylan's 2014 Annual Report, 2015 First Quarter Report, 2015 Second Quarter Report, 2015 Third Quarter Report, and 2015 Annual Report.

175. Defendants Bresch and Campbell provided substantially identical certifications pursuant to Section 302 of SOX for the relevant period with Mylan's 2016 First Quarter Report.

176. Defendants Bresch and Parks provided substantially identical certifications pursuant to Section 302 of SOX for the relevant period with Mylan's 2016 Second Quarter Report.

177. The statements in paragraphs 170 through 176 were materially false and misleading because Mylan did not have effective disclosure controls and procedures between 2014 and 2016.

178. Indeed, any internal controls that Mylan did have in place were woefully deficient to assure that Defendants could not mislead investors about the misclassification of the EpiPen and Mylan's anticompetitive conduct with respect to the EpiPen.

179. The material weaknesses in Mylan's control environment were highlighted by its entry into of a Corporate Integrity Agreement.

180. The CIA required Mylan to make certain enhancements to its Corporate Compliance Program and to implement certain reporting requirements. The CIA required Mylan to, among other things:

- (a) Appoint a senior member of management as an independent Compliance Officer who reports directly to the CEO. The Compliance Officer was to be responsible for “developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements”; “making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Mylan Inc.”; and “monitoring the day-to-day compliance activities engaged in by Mylan as well as for any reporting obligations created under this CIA.”
- (b) Create a Compliance Committee comprised of the Compliance Officer and members of senior management who have responsibility for, among others, the audit and operations departments.
- (c) Pass an annual Board resolution that states the following: “The Board of Directors (or a committee thereof) has made a reasonable inquiry into the operation of Mylan’s Compliance Program during the preceding twelve-month period including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Mylan has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the Corporate Integrity Agreement.”
- (d) Have Mylan’s CFO, Head of Commercial Finance – North America, Head of Government Reporting, Head of Finance, Global Integrated Services – North America, and Director, Accounts Receivable sign annual certifications that their respective business units are compliant with applicable healthcare program requirements and with the obligations of the CIA.
- (e) Develop and implement written policies and procedures regarding the operation of its Compliance Program. The CIA requires that, “[a]t a minimum, the Policies and Procedures shall address appropriate ways to conduct Government Pricing Functions in compliance with all applicable Federal health care program requirements. This includes (a) gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare & Medicaid Services (CMS) and/or the State Medicaid

Programs in connection with the Medicaid Drug Rebate Program, the Medicare program, and as otherwise required by Federal or state government requirements and directives; and (b) the appropriate classification of drugs as Single Source, Innovator Multiple Source, or Non-Innovator Multiple Source drugs for purposes of the Medicaid Drug Rebate Program.”

- (f) Develop a written training plan “that outlines the steps Mylan will take to ensure that: (a) all Covered Persons receive adequate training regarding Mylan’s CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute, and (b) all Relevant Covered Persons receive adequate training regarding: (i) Mylan’s systems and processes relating to Government Pricing Functions; (ii) all applicable Federal health care program requirements relating to Government Pricing Functions; and (iii) Mylan’s systems for gathering relevant data and calculating, verifying, and reporting information to CMS and/or the State Medicaid Programs for purposes of the Medicaid Drug Rebate Program, the Medicare Program, or any other Federal or state government price reporting requirement.”
- (g) Subject each member of the Board to at least two hours of training that addresses “the corporate governance responsibilities of board members and the responsibilities of board members with respect to review and oversight of the Compliance Program.”
- (h) Engage an Independent Review Organization to report on Mylan’s classification of drugs under the MDRP.
- (i) Develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the drugs that are paid for by Medicaid.
- (j) Establish a disclosure program that “includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual’s chain of command any identified issues or questions associated with Mylan’s policies, conduct, practices, or procedures with respect to a Federal health care program requirement believed by the individual to be a potential violation of criminal, civil, or administrative law.” “Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to

ensure that it obtains all necessary information to determine whether a further review should be conducted.”

- (k) Provide written notice to the Office of Inspector General – within thirty days of discovery – “of any ongoing investigation or legal proceeding known to Mylan conducted or brought by a governmental entity or its agents involving an allegation that Mylan has committed a crime or has engaged in fraudulent activities.”
- (l) Provide written notice to the Office of Inspector General – within thirty days of determining that a “Reportable Event” has occurred – of “a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program requirements for which penalties or exclusion may be authorized.”

181. Mylan’s agreement to undertake these improvements to its internal controls highlights the significant deficiencies in its disclosure controls and procedures that needed to be addressed as of the end of 2016 (when Mylan entered into the CIA). The fact that Mylan had to implement these measures demonstrates the falsity of Defendants’ prior certifications concerning the purported effectiveness of Mylan’s disclosure controls and procedures.

ADDITIONAL ALLEGATIONS OF SCIENTER

182. Plaintiffs repeat and reallege each and every paragraph contained above as if set forth herein.

183. Defendants Bresch, Campbell, Malik, Parks, and Sheehan acted with scienter with respect to the materially false and misleading statements, and omissions of material fact, set forth above because they knew, or at the very least recklessly disregarded, that those statements were false when made. As the most senior executives of Mylan during the relevant time period, Defendants’ scienter is imputable to Mylan.

184. During the relevant period, Defendant Bresch was CEO of Mylan, Defendant Malik served as President, Defendants Sheehan and Parks served as Mylan’s CFOs, and

Defendant Campbell served as Mylan's CAO. By virtue of their responsibilities and activities in these positions, Defendants Bresch, Campbell, Malik, Parks, and Sheehan were privy to, and participated in, the fraudulent conduct described herein.

185. The EpiPen was part of Mylan's core business because sales of the EpiPen accounted for a significant and material portion of Mylan's profits during the relevant period, as reflected by the following table:

	2014	2015	2016
EpiPen Operating Profit⁴	\$525,000,000	\$498,000,000	\$671,000,000
Mylan Earnings from Operations	\$1,352,600,000	\$1,460,900,000	\$701,600,000
Percentage	39%	34%	96%

186. Because Mylan's sales of the EpiPen were part of Mylan's core business, Defendants Bresch, Campbell, Malik, Parks, and Sheehan would have had robust knowledge of significant aspects of those sales, including the Medicaid and PBM rebates.

187. Given their high-level positions at the Company and the importance of the EpiPen to Mylan's business, Defendants Bresch, Campbell, Malik, Parks, and Sheehan knew, or recklessly disregarded, that Mylan was misclassifying the EpiPen for purposes of the Medicaid rebate. CMS repeatedly informed Mylan that its classification of the EpiPen as a generic drug for purposes of the MDRP was incorrect. In Andrew Slavitt's October 5, 2016 letter to the Senate Finance Committee, CMS stated unequivocally:

The Center for Medicaid and CHIP Services in *CMS has, on multiple occasions*, provided guidance to the industry and Mylan on the proper classification of drugs and has *expressly told Mylan that the product is incorrectly classified*.

⁴ Based on September 26, 2016 Mylan filing with SEC.

188. CMS likely started informing Mylan of the misclassification as early as 2009, after CMS was informed by the Office of Inspector General that Mylan was misclassifying the EpiPen as a generic drug.

189. Prior to making the material misrepresentations described above, Defendants Bresch, Campbell, Malik, Parks, and Sheehan also knew about, or recklessly disregarded, the DOJ's investigation into Mylan's classification of the EpiPen. The November 2014 DOJ subpoena to Mylan raised serious concerns about a significant part of Mylan's core business. Mylan did not simply ignore that subpoena; rather, by Mylan's own admission, it "complied with various information requests received from the DOJ pursuant to the subpoena." However, Defendants failed to disclose the existence of this investigation to investors for several years.

190. The fact that – just two days after CMS's disclosure to Congress that it had "on multiple occasions . . . expressly told Mylan that the product is incorrectly classified" – Mylan settled with the DOJ for almost half a billion dollars is further evidence of the Individual Defendants' scienter.

191. Defendants Bresch, Campbell, Parks, and Sheehan attested to their robust knowledge of Mylan's sales and pricing activity. Specifically, they signed certifications in Mylan's periodic SEC filings pursuant to SOX. In each of these certifications, Defendants Bresch, Campbell, Parks, and Sheehan stated that the information contained in Mylan's periodic reports was accurate and not misleading. These attestations required knowledge of Mylan's financial statements and the bases of these financial statements, including the bases for Mylan's statements of its sales, revenue and drug pricing. These attestations also required knowledge of Mylan's statements of risk factors and whether those risks had materialized.

192. Indeed, in making such certifications in Mylan's annual reports, Defendants Bresch and Sheehan also attested to their understanding of the rule for classifying drugs under the MDRP. Yet they completely disregarded this rule when it came to the EpiPen.

193. Defendants Bresch and Sheehan also attested to the accuracy of the statements in Mylan's annual reports concerning the purported competition that Mylan faced with respect to the EpiPen. In making these statements, Defendants Bresch and Sheehan knew, or recklessly disregarded, that Mylan was engaging in anticompetitive conduct with respect to the EpiPen. Indeed, according to allegations in the complaint filed in the Class Action on which the Court relied in deciding Defendants first motion to dismiss, a former Director of Costing and Director of Production Planning of Mylan stated that "pricing decisions at Mylan occurred frequently and involved all of Mylan's top executives," and that "the CEO and CFO of Mylan reviewed any price adjustments and had the last word on pricing decisions for Mylan's drugs."

194. Defendants Bresch, Campbell, Malik, Parks, and Sheehan also knew about, or recklessly disregarded, Mylan's ineffective disclosure controls and procedures. The glaring holes in Mylan's disclosure controls and procedures – many of which are addressed in the Corporate Integrity Agreement that Mylan entered into in connection with the DOJ settlement – were the responsibility of Mylan's senior executives. Indeed, Defendants Bresch, Campbell, Parks, and Sheehan all attested that they had designed Mylan's disclosure controls and procedures (or had caused such disclosure controls and procedures to be designed under their supervision), and that they had each evaluated the effectiveness of Mylan's disclosure controls and procedures before certifying to their effectiveness.

195. The numerous investigations and legal actions into Mylan's misclassification of the EpiPen and its anticompetitive conduct with respect to the EpiPen further evidence

Defendants' scienter. Indeed, the court in the EpiPen Antitrust Action recently denied a motion to dismiss antitrust claims against Defendants Mylan and Bresch based, in part, on the very same anticompetitive conduct that is alleged in this Complaint.

PRESUMPTION OF RELIANCE

196. Plaintiff intends to rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things: (a) Defendants made public misrepresentations or failed to disclose material facts during the relevant time period; (b) the omissions and misrepresentations were material; (c) Mylan common stock traded in an efficient market; (d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Mylan common stock; and (e) the Assignors purchased Mylan common stock between the time Defendants misrepresented or failed to disclose material facts and the time when the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

197. The market for Mylan common stock was open, well-developed and efficient at all relevant times. As a result of the aforementioned materially false and misleading statements, Mylan common stock traded at artificially inflated prices during the relevant period. The artificial inflation continued until the time the market fully came to realize the nature and extent of Defendants' misrepresentations concerning the basis for Mylan's financial performance, the amount of the rebates that Mylan was paying to Medicaid for the EpiPen, Defendants' knowledge of the EpiPen misclassification, the potential regulatory scrutiny to which Mylan was subject, the competitiveness of the market for the EpiPen, and the effectiveness of Mylan's disclosure controls and procedures.

198. At all relevant times, the market for Mylan common stock was efficient for the following reasons, among others: (a) Mylan filed periodic reports with the SEC; (b) Mylan

common stock was listed and actively traded on the NASDAQ; (c) numerous analysts followed Mylan; and (d) Mylan regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

199. The Assignors purchased Mylan common stock in reliance on the market price of Mylan common stock, which reflected all the information in the market, including the misstatements by Defendants.

ACTUAL RELIANCE

200. During the relevant period, the Assignors' investment in Mylan common stock was managed by Greenlight. Greenlight made the investment decisions with respect to Assignors' purchases of Mylan common stock. Factors considered by Greenlight in making such decisions included, among other things, Mylan's financial performance and a review of the Company's strengths, weaknesses and opportunities.

201. Prior to making the decision to purchase Mylan common stock, a Greenlight investment analyst actually and justifiably read, reviewed and relied upon (to the extent the referenced documents had been published at the time) the 2013 Annual Report, 2014 Annual Report, 2015 First Quarter Report, 2015 Second Quarter Report, 2015 Third Quarter Report, 2015 Annual Report, 2016 First Quarter Report, and 2016 Second Quarter Report filed by Mylan including (as applicable): (a) statements concerning the basis for Mylan's financial statements; (b) statements about the amount of the rebates that Mylan was paying to Medicaid; (c) statements about the risk of errors in classifying drugs under the MDRP; (d) statements concerning the potential regulatory scrutiny to which Mylan was subject; (e) statements

concerning the competitiveness of the market for the EpiPen; and (f) statements and certifications that Mylan had effective internal controls over disclosure controls and procedures.

202. Greenlight actually and justifiably relied upon the information contained in Mylan's the 2013 Annual Report, 2014 Annual Report, 2015 First Quarter Report, 2015 Second Quarter Report, 2015 Third Quarter Report, 2015 Annual Report, 2016 First Quarter Report, and 2016 Second Quarter Report filed by Mylan (to the extent each such document was on file with the SEC at the time) in making each purchase set forth in Exhibits A through F on behalf of the Assignors.

LOSS CAUSATION

203. As the truth about Mylan's misclassification of the EpiPen and its anticompetitive conduct with respect to the EpiPen gradually and slowly leaked into the market, the price of Mylan common stock dropped precipitously.

204. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff. During the time that the Assignors purchased Mylan common stock, as set forth in Exhibits A through F, the market price of those securities was artificially inflated as a direct result of Defendants' materially false and misleading statements and material omissions. Specifically, Mylan's misrepresentations concerning the basis for Mylan's financial performance, the amount of the rebates that Mylan was paying to Medicaid for the EpiPen, Defendants' knowledge of the EpiPen misclassification, the potential regulatory scrutiny to which Mylan was subject, the competitiveness of the market for the EpiPen, and the assurances of effective disclosure controls and procedures, caused the price of Mylan's common stock to be artificially inflated.

205. As a series of partial but inadequate disclosures were issued partially correcting the prior false and/or misleading statements with respect to the basis for Mylan's financial

performance, the amount of the rebates that Mylan was paying to Medicaid for the EpiPen, Defendants' knowledge of the EpiPen misclassification, the potential regulatory scrutiny to which Mylan was subject, the competitiveness of the market for the EpiPen, and the effectiveness of Mylan's internal disclosure controls and procedures, the price of Mylan stock declined precipitously, and the Assignors were damaged.

206. On August 22, 2016, Senator Klobuchar, the top Democrat on the Senate Judiciary Committee's Antitrust Subcommittee, released a statement calling for the FTC to investigate whether Mylan had violated the antitrust laws in selling the EpiPen. Specifically, Senator Klobuchar pleaded with the FTC to probe whether Mylan "engaged in activity, *such as using incentives or exclusionary contracts with insurers*, distributors, or pharmacies, *to deny an alternative product access to the market.*"

207. That same day, Senator Grassley, the Chairman of the Senate Judiciary Committee, sent a letter to Defendant Bresch, asking that Mylan provide information to Congress concerning its pricing practices with respect to the EpiPen.

208. This government scrutiny over the EpiPen continued over the next two days. On August 23, 2016, Bloomberg reported that the price of Mylan's stock was continuing to drop because U.S. senators were trying to understand how Mylan had been able to exponentially raise the cost of the EpiPen.

209. On August 24, 2016, Senators Collins and McCaskill, on behalf of Senate Special Committee on Aging, sent a letter to Defendant Bresch asking Mylan to provide "any analysis used by Mylan relating to the pricing or market share of EpiPen since 2007."

210. The price of Mylan common stock dropped in response to these partial disclosures. At the close of trading on August 19, 2016, Mylan common stock closed at a price

of \$48.66 per share. At the close of trading on August 22, 2016, Mylan common stock closed at a price of \$47.90 per share, a drop from the previous close of \$0.76 per share. At the close of trading on August 23, 2016, Mylan common stock closed at a price of \$45.62 per share, a drop from the previous close of \$2.28 per share. At the close of trading on August 24, 2016, Mylan common stock closed at a price of \$43.15 per share, a drop from the previous close of \$2.47 per share.

211. On September 2, 2016, Senator Wyden and Representative Pallone sent a letter to HHS Secretary Mathews Burwell, saying that Medicaid may have been grossly overpaying for the EpiPen due to a misclassification by Mylan of the EpiPen as a generic drug for purposes of the MDRP. According to Senator Wyden and Representative Pallone, Mylan may have been incorrectly designating the EpiPen as a generic in the Medicaid program for years, despite being considered a brand-name drug by the FDA. According to the letter, this would mean Mylan has been “vastly underpaying rebates owed to Medicaid for the EpiPen for years.” They concluded the letter by asking HHS for more information about the EpiPen’s classification under the MDRP.

212. The price of Mylan common stock dropped in response to this partial disclosure. At the close of trading on September 1, 2016, Mylan common stock closed at a price of \$41.92 per share. At the close of trading on September 2, 2016, Mylan common stock closed at a price of \$39.97 per share, a drop from the previous close of \$1.95 per share.

213. Mylan immediately denied any misclassification of the EpiPen. In a statement released on September 2, 2016, as the market reacted to the disclosures in Senator Wyden and Representative Pallone’s letter, a Mylan spokeswoman, Nina Devlin, said “Mylan has complied

with all laws and regulations regarding the Medicaid rebate classification” of the EpiPen, and that the EpiPen meets the definition of a N drug under the law.

214. On October 5, 2016, CMS submitted its response to Senator Wyden and Representative Pallone’s information request, which Bloomberg alerted investors to after the markets closed in an article titled, “Mylan Overcharged U.S. on EpiPen for Years, U.S. Says.” The CMS letter stated that, from 2011 to 2015, net Medicaid spending on the EpiPen was approximately \$797 million, which reflected a rebate of only 13% paid by Mylan. According to the letter, Medicaid should have been getting a larger discount of at least 23.1% because the EpiPen was approved under a NDA, has patent protection, and did not have any FDA-approved therapeutic equivalents. Further, CMS stated that it had, “on multiple occasions,” “expressly told Mylan that the product is incorrectly classified.” CMS could not tell Congress at that time exactly how much Mylan had overcharged Medicaid.

215. The price of Mylan common stock dropped in response to this partial disclosure. At the close of trading on October 5, 2016, Mylan common stock closed at a price of \$38.03 per share. At the close of trading on October 6, 2016, Mylan common stock closed at a price of \$36.84 per share, a drop from the previous close of \$1.19 per share.

216. However, Mylan continued to publicly deny that it had misclassified the EpiPen. In response to this letter, Devlin said in an e-mail to Bloomberg that Mylan had previously stated that EpiPen meets the definition of a N drug. According to Devlin, Mylan’s classification of EpiPen as a N drug “is consistent with longstanding written guidance from the federal government.”

217. On October 7, 2016, prior to the opening of the markets, Senator Klobuchar released a statement commenting on a reported \$465 million settlement between the DOJ and Mylan “over the misclassification of the EpiPen.”

218. Later that morning, the *Washington Examiner* released an article titled, “EpiPen maker to pay \$465 million for overcharging feds.” The article quoted Defendant Bresch as saying, “[t]his agreement is another important step in Mylan’s efforts to move forward and bring resolution to all EpiPen Auto-Injector related matters.” The article also revealed that Mylan did not admit wrongdoing in the settlement. Later that day, Mylan issued its official press release addressing the settlement.

219. The price of Mylan common stock dropped in response to this partial disclosure. At the close of trading on October 6, 2016, Mylan common stock closed at a price of \$36.84 per share. At the close of trading on October 7, 2016, Mylan common stock closed at a price of \$35.94 per share, a drop from the previous close of \$0.90 per share.

220. On October 11, 2016, after the close of trading, CNBC reported that Mylan’s settlement with the DOJ had a “\$120 million question attached to it” relating to a six-month grace period during when it was unclear how much in rebates Mylan would owe.

221. The price of Mylan common stock dropped in response to this partial disclosure. At the close of trading on October 11, 2016, Mylan common stock closed at a price of \$38.31 per share. At the close of trading on October 12, 2016, Mylan common stock closed at a price of \$37.07 per share, a drop from the previous close of \$1.24 per share.

222. The above partial corrective disclosures also reflect a materialization of foreseeable risks that Defendants concealed through their materially false and misleading statements and material omissions.

223. Defendants represented to investors the purported basis for Mylan's financial performance, the amount of the rebates that Mylan was purportedly paying to Medicaid, the purported risk of error in classifying drugs under the MDRP, and the potential regulatory scrutiny to which Mylan was subject in classifying the EpiPen. In making these representations, Defendants concealed the foreseeable risk that Mylan's misclassification of the EpiPen would result in government action to recoup the rebate payments that Mylan failed to make to Medicaid. Beginning with the September 2, 2016 partial disclosure that Mylan had misclassified the EpiPen for years, that foreseeable risk gradually materialized, thus causing Mylan's stock price to decline as detailed above.

224. Defendants also sought to reassure investors that the market for the EpiPen was competitive. In making these representations, Defendants concealed the foreseeable risk that Mylan's anticompetitive conduct with respect to the EpiPen would result in increased government scrutiny over the price of the EpiPen. Beginning with the August 22, 2016 partial disclosure of the increased government scrutiny over the EpiPen pricing, that foreseeable risk gradually materialized, thus causing Mylan's stock price to decline as detailed above.

225. Defendants also sought to reassure investors that Mylan's internal controls were effective. In doing so, they concealed the foreseeable risk that Mylan's lack of meaningful controls would result in increased government scrutiny over the price of the EpiPen and government action to recoup the rebate payments that Mylan failed to make to Medicaid. Beginning with the August 22, 2016 partial disclosure of the increased government scrutiny over the EpiPen pricing and continuing through the partial disclosures concerning Mylan's misclassification of the EpiPen, that foreseeable risk gradually materialized, thus causing Mylan's stock price to decline as detailed above.

NO SAFE HARBOR

226. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not “forward-looking statements” nor were they identified as “forward-looking statements” when made. Nor was it stated with respect to any of the statements forming the basis of this Complaint that actual results “could differ materially from those projected.” To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Mylan who knew that those statements were false when made.

FIRST CAUSE OF ACTION

**Violations of Section 10(b) of the Exchange Act and Rule 10b-5
Against All Defendants**

227. Plaintiff repeats and realleges each and every allegation above as if set forth herein.

228. This cause of action is brought against Defendants Mylan, Bresch, Campbell, Malik, Parks, and Sheehan for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j, and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

229. Defendants Mylan, Bresch, Campbell, Malik, Parks, and Sheehan both directly and indirectly used the means and instrumentalities of interstate commerce in the United States to make the materially false and misleading statements and omissions of material fact alleged herein to: (i) deceive the investing public, including the Assignors, as alleged herein; (ii) artificially inflate and maintain the market price of Mylan common stock; and (iii) cause the Assignors to purchase Mylan common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Mylan, Bresch, Campbell, Malik, Parks, and Sheehan took the actions set forth above.

230. Defendants Mylan, Bresch, Campbell, Malik, Parks, and Sheehan both directly and indirectly: (i) employed devices, schemes and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of Mylan common stock in an effort to artificially inflate and maintain the market prices for Mylan common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5.

231. By virtue of their high-level positions at the Company, Bresch, Campbell, Malik, Parks, and Sheehan were authorized to make public statements, and made public statements on Mylan's behalf. These senior executives were privy to and participated in the creation, development, and issuance of the materially false and misleading statements alleged herein, and/or were aware of the Company's and their own dissemination of information to the investing public that they recklessly disregarded was materially false and misleading.

232. In addition, Mylan, Bresch, Campbell, Malik, Parks, and Sheehan had a duty to disclose truthful information necessary to render their affirmative statements not materially

misleading so that the market price of the Company's securities would be based on truthful, complete and accurate information.

233. Defendants Mylan, Bresch, Campbell, Malik, Parks, and Sheehan acted with knowledge or reckless disregard for the truth of the misrepresented and omitted facts alleged herein, in that they failed to ascertain and disclose the facts, even though such facts were known or readily available to them. Defendants Mylan's, Bresch's, Campbell's, Malik's, Parks', and Sheehan's material misrepresentations and omissions were done knowingly and/or recklessly, and had the effect of concealing the truth with respect to Mylan's operations, business, performance and prospects from the investing public, including concerning the basis for Mylan's financial performance, the amount of the rebates that Mylan was paying to Medicaid for the EpiPen, Defendants' knowledge of the EpiPen misclassification, the potential regulatory scrutiny to which Mylan was subject, the competitiveness of the market for the EpiPen, and the effectiveness of Mylan's disclosure controls and procedures. By concealing these material facts from investors, Mylan, Bresch, Campbell, Malik, Parks, and Sheehan supported the artificially inflated price of Mylan's common stock.

234. The dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, artificially inflated the market price of Mylan's common stock. In ignorance of the fact that the market prices were artificially inflated, and relying directly or indirectly upon the materially false and misleading statements made by Defendants, and upon the integrity of the market in which the Company's securities trade, or upon the absence of material adverse information that was recklessly disregarded by Defendants, but not disclosed in public statements by Defendants, the Assignors purchased Mylan common

stock at artificially inflated prices. As a series of partial but inadequate disclosures were issued, the price of Mylan's securities substantially declined.

235. At the time of the material misrepresentations alleged herein, the Assignors were ignorant of their falsity, and believed them to be true. Had the Assignors known the truth with respect to the business, operations, performance and prospects of Mylan, which was concealed by Defendants, the Assignors would not have purchased Mylan common stock, or if they had purchased such securities, they would not have done so at the artificially inflated prices that they paid.

236. By virtue of the foregoing, Defendants Mylan, Bresch, Campbell, Malik, Parks, and Sheehan have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

237. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has suffered damages in connection with the Assignors' transactions in the Company's securities.

238. Taking into account, *inter alia*, tolling of the limitations period by the filing of the class action complaint against Defendants in the Class Action, Plaintiff has brought this claim within two years of discovery of the violations alleged herein, and within five years of the violations alleged herein. Consequently, this action is timely.

SECOND CAUSE OF ACTION

Violations of Section 20(a) of the Exchange Act Against Defendants Bresch, Campbell, Malik, Parks, and Sheehan

239. Plaintiff repeats and realleges each and every allegation above as if set forth fully herein.

240. This Cause of Action is asserted against Defendants Bresch, Campbell, Malik, Parks, and Sheehan and is based upon Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

241. Each of Defendants Bresch, Campbell, Malik, Parks, and Sheehan was a controlling person of Mylan within the meaning of Section 20(a) of the Exchange Act.

242. By virtue of their high level positions, and their ownership and contractual rights, substantial participation in, and/or awareness of, the Company's operations and/or knowledge or reckless disregard of the materially false and misleading statements filed with the SEC and disseminated to the investing public, Defendants Bresch, Campbell, Malik, Parks, and Sheehan had the power to influence and control, and did in fact influence and control, directly or indirectly, the decision-making of the Company.

243. Defendants Bresch, Campbell, Malik, Parks, and Sheehan were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged herein to be materially false and misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected. In particular, Defendants Bresch, Campbell, Malik, Parks, and Sheehan each had direct and supervisory involvement in the day-to-day operations of the Company, and therefore are presumed to have had the power to control or influence the particular false and misleading statements and omissions giving rise to the securities violations alleged herein.

244. Defendants Bresch, Campbell, Malik, Parks, and Sheehan culpably participated in Mylan's violation of Section 10(b) and Rule 10b-5 with respect to the First Cause of Action.

245. By reason of the conduct alleged in the First Cause of Action, Mylan is liable for violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, and Defendants Bresch, Campbell, Malik, Parks, and Sheehan are liable pursuant to Section 20(a) based on their control of Mylan.

246. Defendants Bresch, Campbell, Malik, Parks, and Sheehan are liable for the aforesaid wrongful conduct, and are liable to Plaintiff for the substantial damages suffered in connection with the Assignors' purchases of Mylan common stock.

247. Taking into account, *inter alia*, tolling of the limitations period by the filing of the class action complaint against Defendants Bresch, Campbell, Malik, Parks, and Sheehan in the Class Action, Plaintiff has brought this claim within two years of discovery of the violations alleged herein, and within five years of the violations alleged herein. Consequently, this action is timely.

THIRD CAUSE OF ACTION

Violations of Section 18 of the Exchange Act Against All Defendants

248. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1-139, 150-181, and 200-226 above as if set forth herein.

249. As alleged herein, Defendants Bresch, Malik, and Sheehan caused statements to be made in Mylan's 2013 Annual Report, and the SOX certifications filed with that report, that were, at the time and in light of the circumstances under which they were made, false or misleading with respect to material facts.

250. As alleged herein, Defendants Bresch, Malik, and Sheehan caused statements to be made in Mylan's 2014 Annual Report, and the SOX certifications filed with that report, that were, at the time and in light of the circumstances under which they were made, false or misleading with respect to material facts.

251. As alleged herein, Defendants Bresch, Malik, Campbell and Sheehan caused statements to be made in Mylan's 2015 Annual Report, and the SOX certifications filed with that

report, that were, at the time and in light of the circumstances under which they were made, false or misleading with respect to material facts.

252. As alleged herein, Defendants Bresch and Sheehan caused statements to be made in Item 4 of, and the SOX certifications filed with, Mylan's 2015 First Quarter Report, 2015 Second Quarter Report, and 2015 Third Quarter Report, that were, at the time and in light of the circumstances under which they were made, false or misleading with respect to material facts.

253. As alleged herein, Defendants Bresch and Campbell caused statements to be made in Item 4 of, and the SOX certifications filed with, Mylan's 2016 First Quarter Report that were, at the time and in light of the circumstances under which they were made, false or misleading with respect to material facts.

254. As alleged herein, Defendants Bresch and Park caused statements to be made in Item 4 of, and the SOX certifications filed with, Mylan's 2016 Second Quarter Report that were, at the time and in light of the circumstances under which they were made, false or misleading with respect to material facts.

255. In purchasing Mylan's common stock, the Assignors' analyst team actually and justifiably read, and had direct eyeball reliance on, Mylan's 2013 Annual Report, 2014 Annual Report, 2015 First Quarter Report, 2015 Second Quarter Report, 2015 Third Quarter Report, 2015 Annual Report, 2016 First Quarter Report, and 2016 Second Quarter Report (to the extent published at the time of purchase).

256. Specifically, an investment analyst at Greenlight read and actually relied upon information contained in Mylan's 2013 Annual Report, 2014 Annual Report, 2015 First Quarter Report, 2015 Second Quarter Report, 2015 Third Quarter Report, 2015 Annual Report, 2016 First Quarter Report, and 2016 Second Quarter Report (to the extent each such document was on

file with the SEC at the time) in making each purchase set forth in Exhibits A through F on behalf of the Assignors, as further described above in paragraphs 200 through 202.

257. In ignorance of the falsity of Defendants' statements, or of the true facts, the Assignors purchased Mylan common stock in actual, justifiable, eyeball reliance upon Defendants' representations.

258. Defendants' materially false and misleading statements and omissions of material fact artificially inflated the price of Mylan common stock.

259. Had they known the true facts, the Assignors would not have purchased Mylan common stock and/or would not have purchased the shares at the inflated prices they paid.

260. Upon disclosure of the true facts, the price of Mylan common stock dropped, and Plaintiff has suffered damages in an amount to be proven at trial.

261. By reason of the foregoing, Defendants Mylan, Bresch, Campbell, Malik, Parks, and Sheehan are liable to Plaintiff for violations of Section 18 of the Exchange Act, 15 U.S.C. §78r.

262. Taking into account, *inter alia*, tolling of the limitations period by the filing of the class action complaint against Defendants Mylan, Bresch, Campbell, Malik, Parks, and Sheehan in the Class Action, Plaintiff has brought this claim within two years of discovery of the violations alleged herein, and within five years of the violations alleged herein. Consequently, this action is timely.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests relief and judgment, as follows:

- (a) Awarding compensatory damages against Defendants for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon;
- (b) Awarding Plaintiff its reasonable costs and expenses incurred in this action; and
- (c) Such other and further relief as the Court may deem just and proper.

JURY DEMAND

The Plaintiff hereby demands a trial by jury as to all issues so triable.

Dated: February 26, 2019
New York, New York

LOWENSTEIN SANDLER LLP

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